

851 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-0085

## 6096 '98 SEP 11 P1:53

August 31, 1998

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204 6/01/

DECEWE)

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Rexall Sundown, Inc. located at 851 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 within the past 30 days marketed a dietary supplement bearing the following additional statement(s) on the label and/or in the labeling:

Memory Care: [It] promotes healthy brain function and memory. Phosphatidylserine (PS) is a naturally occurring nutrient that is essential to the functioning of all cells in the body, particularly in the brain where it is most concentrated. Natural aging and nutritional deficiencies may decrease PS levels in the brain resulting in Age-Associated Memory Impairment (AAMI).

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

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Vice President of Regulatory Affairs

and Corporate Counsel

Enclosure

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